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09/744,502	07/13/2001	Victor Rubio Susan	4512/00012	8777

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225 FRANKLIN ST
BOSTON, MA 02110

EXAMINER

MARX, IRENE

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 07/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/744,502

Applicant(s)

RUBIO SUSAN ET AL.

Examiner

Irene Marx

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 May 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-25, 34 and 35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 11-25 and 34-35 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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The application should be reviewed for errors.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5/28/04 has been entered.

In keeping with scientific custom, the names of genera and species of microorganisms should be underlined or italicized throughout the specification and claims.

Claims 11-25 and 34-35 are being considered on the merits.

Claims 26-33 are cancelled.

The disclosure is objected to because of the following informality: In the specification at page 32, last line the word “???strain” is used.

Appropriate correction is required. No new matter may be added.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The amendment filed 10/29/03 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: The material at page 4 starting at line 27 and the material at page 14, line 15.

The issue of new matter is also raised by the recitation in claims 24 and 25 regarding the sale of *Rhizoctonia*. No basis or support is found in the present as-filed specification for this material.

Applicant is required to cancel the new matter in the reply to this Office Action.

Response to Arguments

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Applicant's arguments have been fully considered but they are not deemed to be persuasive.

Applicant's assertions that the skilled person would recognize that the sequences according to SEQ ID NO: 1 to 14 were target sequences from the isolates themselves and not primers directed thereto and that they are within SEQ ID NO: 15 to 25 is noted. However no alignment or other evidence is provided to substantiate these contentions for all of the sequences of interest. The sequences are not short enough to make the alleged relationship readily apparent. Moreover, applicants averred in the oath that the specification had been reviewed.

The alignment presented is not informative regarding SEQ. ID. No: 3, 4 and 6.

Therefore the rejection is deemed proper and it is adhered to.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 11-25 and 34-35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 11-25 are vague and indefinite in the recitation of "protection of a plant from pathogenic fungi", because the degree and extent of protection is not set forth with any particularity, even when interpreting the claims in light of the specification.

Claims 34 and 35 are incomplete in that they are directed to a "method of protecting a seed, plant or seedling", without an indication of whether the protecting is from fungi, drought, osmotic stress, etc. In addition, the degree and extent of protection is not set forth with any particularity, even when interpreting the claims in light of the specification.

Claim 11 is incomplete in lacking an inoculation step. It is noted that *Rhizoctonia* are provided and that there is a step of "allowing ... to grow with the plant". However, there is no clear claim indication to specify that the plant is inoculated with the strain and that the strain subsequently grows on the plant or on which part of the plant for protection to occur. It is uncertain that the effect is systemic, such that if a claim designated strain of *Rhizoctonia* is provided on a leaf or a pine needle, a tree, for example, will be protected from all pathogenic

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fungi or for how long. Thus the claim appears incomplete in the absence of a positive limitation of growth of the viable strain and a better definition of the locus of “providing”.

Claims 20-23 are confusing in that the distinction between “allowing to grow with the plant” in claim 11 and “allowing to be colonized” in claims 20 and 21 is unclear, particularly since a seed is not properly a “plant”. The antecedent basis is unclear in this context for “allowing the seed to be colonized”. If the seeds produced by the plant protected in claim 11 are to be colonized, this material should be clearly and particularly claimed.

Claim 35 is incomplete and confusing in that it is unclear what is intended by “mycelium of a viable binucleate *Rhizoctonia* strain”, since it is uncertain that a tiny fragment of a mycelium even of a viable binucleate *Rhizoctonia* would be protective for plants when provided in traces and no matter how dilute. It is also uncertain whether even if a strain is viable, a mycelium fragment thereof is viable and reproducibly and predictably capable of protection as required. It appears that what is required for protection is a viable binucleate *Rhizoctonia* strain.

Claims 24 and 25 are vague and indefinite because the claim requires the binucleate *Rhizoctonia* to be sold to a farmer or to an entity other than a commercial grower during the process of protecting a plant from pathogenic fungi and/or while the *Rhizoctonia* strain is growing with the plant. There is no clear indication that the plant is included in the sale. If the strain is growing with a tree the process appears at least cumbersome.

Claims 24 and 25 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. There is no clear correlation between the protecting of a plant and the selling of a fungus. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claims 11, 34 and 35 are vague and indefinite in the recitation of “90% homologous”. In the Response, applicants argue “identity” or “similarity” in various contexts (See, e.g., Response, page 11, paragraph 1; page 12, paragraph 2). However, this is not the claim designated language.

Claim 17 is incorrect in indicating that “the plant is a 33”. Flowers are parts of plants, rather than a type of plant. Do applicants intend “the plant is a flowering plant”?

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Claim 19 fails to find proper antecedent basis in claim 11 for inoculating plant seeds, since claim 11 is directed to the inoculation

Response to Arguments

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

With respect to the specification at page 17, the process depicted is directed to initial colonization of a plant for a period of three days and subsequent inoculation with a pathogenic strain. In the claims all that is recited is "allowing colonization". The term "allowing" in this context appears redundant because inoculation with a viable strain normally would result in growth or colonization unless the site is inhospitable, such that the strain remains dormant at best or ceases to be viable. Therefore, the additional step of "allowing colonization" appears meaningless or redundant, unless unspecified conditions are intended, which are not delineated with sufficient clarity.

Claims 11-25 and 34-35 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn to protection of plants with strains characterized as having an ITS1 DNA which has 90% homology to SEQ ID NO:20. In contrast, the specification only provides guidance regarding the use of strains having a specific sequence, in this instance, SEQ ID NO 20 (Specification page 5, paragraph 4). No guidance is presented for the alteration of any part of any recited sequences having 90% homology or of SEQ ID NO:20, specifically. No guidance is presented regarding the evaluation of strains selected at random for the required homology to SEQ ID NO:20 or regarding which part of that sequence is required to result in effective protection of all plants with any *Rhizoctonia* strain. Given the claim breadth and lack of guidance as discussed above, the specification fails to provide an adequate written description of the claimed invention.

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See *University of California v. Eli Lilly and Co.*, 43 USPQ2d 1398 (Fed. Cir. 1997), which teaches that the disclosure of a process for obtaining cDNA from a particular organism and the description of the encoded protein fail to provide an adequate written description of the actual cDNA from that organism which would encode the protein from that organism, despite the disclosure of a cDNA encoding that protein from another organism.

See *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ 2d 1016 at 1021 and 1027, (Fed. Cir. 1991) at page 1021, where it is taught that a gene (or promoter) is not reduced to practice until the inventor can define it by "its physical or chemical properties" (e.g. a DNA sequence), and at page 1027, where it is taught that the disclosure of a few gene sequences did not enable claims broadly drawn to any analog thereof.

Moreover, there is no clear indication on this record that strains having the required homology and which are suitable for plant protection are freely available to the public. Applicant appears to have deposited certain strains under Budapest Treaty (Specification pages 5-6). However, the record does not clarify which strain(s) are encompassed by the invention as claimed. Once suitable strains are identified, for compliance with the rule, it must be averred that deposited material has been accepted for deposit under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the purpose of Patent Procedure (e.g. see 961 OG 21, 1977) and that all restrictions on the availability to the public of the material so deposited will be irrevocably removed upon the granting of a patent. MPEP 2403.

Additionally, the deposit must be referred to in the body of the specification and be identified by deposit (accession) number, date of deposit, name and address of the depository and the complete taxonomic description.

Response to Arguments

Applicant's arguments as they pertain to the above rejection have been fully considered but they are not deemed to be persuasive.

With respect to the written description rejection, applicant argues that a representative of the genus of sequences having at least 90% homology to SEQ ID NO:20 are recited in the specification. However, these "representative" strains are not available to the public.

Applicant states that strains F5, F6, S6, S1, F1, which are strains within the scope of the invention, were deposited under Budapest Treaty. However, there is no averment of record that

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all restrictions on the availability to the public of the material so deposited will be irrevocably removed upon the granting of a patent. MPEP 2403. In addition, there is no clear correlation between strain Eab-SI and strain Eab-S1 CECT 20323, while the nature of strain Eab-F5 could not readily be determined. Therefore, applicant's arguments are without merit regarding the deposit issue.

While all of the strains deposited show some protective effect, it is clear from the experiments disclosed in the specification that even the strains specifically tested are not protective for all plants against all pathogenic fungi, as claimed. For example, the results show that strains Eab-S6 and Eab-F5 are the most protective against certain pathogens on wheat (page 29) and that strains Eab-S6 and Eab-F6 are the most protective against certain pathogens on rape, (page 34). The effects on other plants and on other fungal pathogens are not disclosed.

It would require undue experimentation for one of ordinary art to test all strains of *Rhizoctonia* to determine if they are binucleate and then determine whether it has an ITS1 sequence which is at least 90% homologous with SEQ ID NO:20, particularly in view of the pervasive reclassification of members of *Rhizoctonia* allegedly to include strains of *Ceratobasidium albasitensis*, the Eab F1 isolate.

From these and other experiments it is clear that the strains are not protective for all plants against all pathogenic fungi, as claimed.

Therefore the rejection is deemed proper and it is adhered to.

Claims 11-13, 18, 19-23, and 34-35 are rejected under 35 U.S.C. 102(b) as being anticipated by Herr (1988) or Cardoso *et al.* (1987) for the reasons as stated in the last Office action and the further reasons below.

The claims are directed to the protection of plants from fungi by using biocontrol with binucleate *Rhizoctonia* having an ITS1 sequence which is at least 90% homologous with SEQ ID NO. 20.

Response to Arguments

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

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On the one hand applicants have argued that the designation *Rhizoctonia* encompass strains other than those specifically designated as such, because otherwise the strains disclosed herein could not be included within this grouping. On the other hand, applicants now argue that the strains of the references are excluded alleging that they are they are multinucleate rather than binucleate, because they belong to *Thanatephorus*. However, the Cardoso reference relied upon, merely states that their strain BNR “resembles” *Thanatephorus*. From this disclosure it cannot be reasonably concluded that the disclosed strain is multinucleate and thus outside of the claimed invention as alleged (Response, page 13, paragraph 4). The reasoning used to cluster the strains disclosed by Herr with those of Cardoso is not set forth with sufficient particularity. Thus the arguments fail to demonstrate with objective evidence that Herr and Cardoso fail to disclose binucleate *Rhizoctonia* strains having at least 90% homology to SEQ ID: 20. The contentions by counsel with respect to a lack of enabling disclosure in Herr because the author failed to deposit, characterize or describe the binucleate strains obtained are noted. However, these arguments by counsel have not been substantiated with appropriate evidence. It is well settled that arguments by counsel do not constitute evidence. Did applicant attempt to obtain any of the disclosed strains, for example.

Contrary to applicant’s contentions, there is no clear correlation between strains having at least 90% homology to a sequence of SEQ ID NO. 20 and protective properties of biocontrol against fungi.

The Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether or not applicants' cultured strains differ and, if so, to what extent, from the strains discussed in the references. Accordingly, inasmuch as the examiner has established that the prior art strain, which is of the same genus *Rhizoctonia* as that claimed, likewise shares the property of being able to protect fungi from pathogens, she has reasonably demonstrated a reasonable likelihood/possibility that the compared strains are either identical or sufficiently similar that whatever differences exist are not patentably significant. Therefore, the burden of establishing anticipation/non-obviousness by objective evidence shifted to Applicants. Applicants have not met that burden.

Applicant has not demonstrated with objective evidence that the strains provided by Herr or Cardoso *et al.* fail to possess at least 90% homology to a sequence of SEQ ID NO. 20.

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Therefore the rejection is deemed proper and it is adhered to.

Claims 11-25 and 34-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Herr taken with Cardoso. for the reasons as stated in the last Office action and the further reasons below.

Response to Arguments

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

The teachings of Herr and Cardoso are discussed *supra*.

Applicants argue broadly that there is no motivation or suggestion in Herr and Cardoso to modify the applied references to arrive at Applicants' invention. However, one of ordinary skill in the art would have been motivated at the time the claimed invention was made to protect any plant from pathogenic fungi with the reference strains which are disclosed as being non-pathogenic and which would reasonably be expected to protect plants other than those disclosed from pathogenic fungi, at least to some extent. With respect to the sale of the fungus and/or plant, there would have been compelling motivation for one of ordinary skill in the art at the time the claimed invention was made to sell useful strains of microorganisms, particularly those which have agricultural application, for the intended benefit of recovering at least to some extent the cost of the research invested in identifying and selection of the strain ..

Therefore the rejection is deemed proper and it is adhered to.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (571) 272-0919. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Irene Marx

**IRENE MARX
PRIMARY EXAMINER**